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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,563	09/26/2005	Jouji Kokuzawa	082386-000100US	7075

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EXAMINER
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SAJJADI, FEREDOUN GHOTB

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,563	<b>Applicant(s)</b> KOKUZAWA ET AL.	
	<b>Examiner</b> Fereydoun G. Sajjadi	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/9/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to papers filed December 6, 2006. Applicant's response to restriction requirement of November 6, 2006 has been entered. No claims were cancelled, amended, or newly added. Claims 1-14 are pending in the application.

#### ***Election/Restrictions***

Applicants' election of Group II (claims 4-8), directed to a method of culturing, proliferating and differentiating neural stem cells in medium comprising hepatocytes growth factor, without traverse, is acknowledged. Applicants' elections for the species of "FGF-2 as a second growth factor, ventricular neural tissue and Parkinson's as the neurological disorder, also without traverse, is further acknowledged. Claims 1-3 and 9-14 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions. As the requirement for restriction is deemed proper, the election requirement is maintained and hereby made Final.

Applicant timely responded to the restriction (election) requirement in the Paper filed December 6, 2006. Claims 4-8 are currently under examination.

#### ***Claim Objections***

Claims 4-6 are objected to because of the following informalities: the claims refer to the growth medium of claim 1, which is a withdrawn claim. Applicants are required to amend the claims to recite all the limitations for the culture medium of claim 1.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects

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for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Csete et al. (U.S. Patent No.: 6,589,728; filed Jan. 31, 2001).

Csete et al. teach a method for isolating, maintaining, enriching and differentiating stem or precursor central nervous system cells from fetal rat brain, that are dissociated to a single-cell suspension and plated on tissue culture dishes in medium containing bFGF. To induce differentiation to neurons and glia, the media containing bFGF is removed and replaced with media lacking bFGF (Abstract and column 15). The authors state that the medium for isolation, proliferation and differentiation of the stem cells may be supplemented with a variety of growth factors, cytokines and serum, that include hepatocytes growth factor (HGF) (column 7). Csete et al. further teach that the isolated progenitor cells may optionally be manipulated to express desired gene products, by transfection prior to expansion and differentiation (column 12), which constitutes the genetic modification of the cells.

Therefore by teaching all the limitations of claims 4-6 and 8, Csete et al. anticipate the instant invention as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 7 is rejected under 35 U.S.C. §103(a) as being unpatentable over Csete et al. (U.S. Patent No.: 6,589,728; filed Jan. 31, 2001), in view of Luskin (U.S. Patent No.: 5,753,505; filed Jul. 6, 1995).

Csete et al. disclose a method for isolating, maintaining, enriching and differentiating stem or precursor cells from fetal rat brain, comprising culturing in medium containing hepatocytes growth factor (HGF) (Abstract and columns 7 and 15). While Csete et al. do not describe the isolation of the neural stem cells from ventricular tissue, the authors state that suitable solid tissues include the brain and central nervous tissue from which neurons and other supporting cells are derived (column 5).

Luskin describes a method of obtaining neuronal progenitor cells comprising isolating the cells from portions of a mammalian brain that is the equivalent of the anterior portion of the subventricular zone surrounding the ventricle of a neonatal rat brain (column 4).

Therefore, a person of ordinary skill in the art would have been motivated to combine the teachings of Csete et al. and Luskin to isolate, culture, proliferate and differentiate neural stem cells from ventricular tissue, as such tissue was specifically identified as a desirable source of neural stem cells. A person of ordinary skill in the art, having combined the neural stem cell culture method of Csete et al., with the stem cells derived from ventricular tissue, as taught by Luskin, would be able to practice the instantly claimed method, to proliferate and differentiate the progenitor cells of the instantly claimed invention into neurons and glia, with a reasonable expectation of success.

Thus it would have been *prima facie* obvious for a person of ordinary skill in the art, to apply the neural stem cell method of Csete et al. to stem cells derived from neural ventricular tissue, as taught by Luskin at the time of the instant invention.

### ***Conclusion***

**Claims 4-8 are not allowable.**

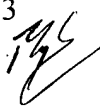
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is (703) 272-3311. The examiner can normally be reached on 7:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fereydoun G. Sajjadi, Ph.D.  
Examiner, USPTO, AU 1633



ANNE M. WEHBE PH.D.  
PRIMARY EXAMINER

